DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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October 24, 2014

RenovoRx, Inc.
C/O Ronald S. Warren
Experien Group, LLC.
755 N. Mathilda Avenue, Suite 100
Sunnyvale, CA 94085

Re: K141175
Trade/Device Name: RenovoCath™ RC120 Catheter
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: II
Product Code: MJN
Dated: August 29, 2014
Received: September 2, 2014

Dear Ronald S. Warren:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kenneth J. Cavanaugh -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141175

Device Name
RenovoCath™ RC120 Catheter

Indications for Use *(Describe)*
The RenovoCath™ RC120 Catheter is intended for the isolation of blood flow and delivery of fluids, including diagnostic and/or therapeutic agents, to selected sites in the peripheral vascular system. The RenovoCath™ RC120 is intended for general intravascular use in the peripheral vasculature in arteries 3mm and larger. The RenovoCath™ RC120 is intended for use in arteries from 3mm in diameter for vessel entry and to occlude vessels ranging between 4mm to llmm in diameter.
The diagnostic and/or therapeutic agents are to be used in accordance with specifications outlined by the respective agent manufacturer.
The RenovoCath™ RC120 Catheter is not intended for use in coronary and intracranial arteries.
The RenovoCath™ RC120 Catheter is not intended for embolic protection or as an aspiration catheter.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Notification: K141175

GENERAL INFORMATION

Applicant:
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U.S.A.
Phone: 1-650-284-4433

Contact Person:
Ronald S. Warren
Regulatory Consultant for RenovoRx, Inc.
Experien Group, LLC.
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Sunnyvale, CA 94085
U.S.A.
Phone: 1-408-505-3926
FAX: 1-408-400-0865

Date Prepared: May 5, 2014

DEVICE INFORMATION

Trade/Proprietary Name:
RenovoCath™ RC120 Catheter

Generic/Common Name:
Catheter, Intravascular Occluding, Temporary

Classification:
21 CFR§870.4450, Vascular clamp

Product Code:
MJN, Catheter, Intravascular Occluding, Temporary

PREDICATE DEVICE(S)

ThermopeutiX, Inc. TAPAS Catheters (K112219) ("TAPAS Catheter")

INDICATIONS FOR USE

The RenovoCath™ RC120 Catheter is intended for the isolation of blood flow and delivery of fluids, including diagnostic and/or therapeutic agents, to selected sites in the peripheral vascular system. The RenovoCath™ RC120 is intended for general intravascular use in the peripheral vasculature in arteries 3mm and larger. The RenovoCath™ RC120 is intended for use in arteries from 3mm in diameter for vessel entry and to occlude vessels ranging between 4mm to 11mm in diameter.

The diagnostic and/or therapeutic agents are to be used in accordance with specifications outlined by the respective agent manufacturer.

The RenovoCath™ RC120 Catheter is not intended for use in coronary and intracranial arteries.

The RenovoCath™ RC120 Catheter is not intended for embolic protection or as an aspiration catheter.

PRODUCT DESCRIPTION

The RenovoCath™ RC120 Catheter ("RenovoCath") is a multi-lumen, dual-balloon catheter. The RenovoCath is designed for targeted delivery of fluids, including diagnostic and/or therapeutic agents, to selected sites in the peripheral vascular system. The distance between the proximal and distal balloons is adjustable. The RenovoCath is provided with two off-the-shelf 3cc syringes that facilitate precise inflation of the balloons under fluoroscopic guidance.

SUBSTANTIAL EQUIVALENCE

The indications for use for the predicate device are substantially equivalent to the proposed indications for use for the RenovoCath. Both devices have the same intended use and similar technological characteristics. Any differences in the technological characteristics between the devices do not raise any new issues of safety or effectiveness. Thus, the RenovoCath is substantially equivalent to the predicate device.

TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

All necessary bench testing was conducted on the RenovoCath to support a determination of substantial equivalence to the predicate device. Testing included biocompatibility, sterilization, validation, shipping and packaging, accelerated aging, and design verification testing. Design verification testing included the following:

- Visual inspection
- Dimensional verification
- Insertion and tracking testing
- Balloon performance verification
- Infusion flow rate testing
- Simulated use testing
- Bonds strength testing
- Infusion port burst testing

The collective results of the testing demonstrate that the RenovoCath meets its specifications and performs as intended. In addition, the collective bench testing demonstrates that the RenovoCath does not raise new questions of safety or effectiveness as compared to the predicate device.

CONCLUSION

The RenovoCath has the same intended use and similar technological characteristics as the TAPAS Catheter predicate device. The RenovoCath has been tested to ensure that it performs as intended and that the technological difference does not raise new issues of safety or effectiveness. As such, the RenovoCath is substantially equivalent to the TAPAS Catheter predicate device.

SUMMARY

The RenovoCath is substantially equivalent to the predicate device.